Commission Implementing Regulation (EU) 2020/1771 of 26 November 2020 approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1771

of 26 November 2020

approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014[(2)] establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes peroxyoctanoic acid, to be renamed reaction mass of peracetic acid and peroxyoctanoic acid, as the result of its evaluation.

(2) Reaction mass of peracetic acid and peroxyoctanoic acid has been evaluated for use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product-type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency (‘the Agency’) on 2 January 2019.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency[(3)] on 4 March 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 2, 3 and 4 containing reaction mass of peracetic acid and peroxyoctanoic acid may be expected to meet the criteria laid down in point (b) of Article 19(1) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve reaction mass of peracetic acid and peroxyoctanoic acid for use in biocidal products of product-types 2, 3 and 4, subject to compliance with certain specifications and conditions.

(7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Reaction mass of peracetic acid and peroxyoctanoic acid is approved as an active substance for use in biocidal products of product-types 2, 3 and 4 subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 November 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

<table>
<tr><th>Common Name</th><th>IUPAC NameIdentification Numbers</th><th colspan="3">Minimum degree of purity of the active substance[a]</th><th>Date of approval</th><th>Expiry date of approval</th><th>Product type</th><th>Specific conditions</th></tr>
<tr><td>Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)</td><td>IUPAC name: Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)
EC No: 201-186-8 and 450-280-7
CAS No: 79-21-0 and 33734-57-5</td><td colspan="3">The minimum purity of the active substance is not relevant as the active substance is a double equilibrium using hydrogen peroxide, acetic acid and octanoic acid as starting materials. The specifications correspond to a range of concentration.
<table><tr><th colspan="2">Components</th><th>Specifications range content (%w/w)</th></tr><tr><td>Active substance</td><td>Peracetic acid</td><td>1,8–13,9</td></tr><tr><td>Active substance</td><td>Peroxyoctanoic acid</td><td>0,15–2,42</td></tr><tr><td>Relevant impurity</td><td>Hydrogn peroxyde</td><td>1,1–25,45</td></tr></table></td><td>1 April 2022</td><td>31 March 2032</td><td>2</td><td>The authorisations of biocidal products are subject to the following conditions:
(a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level</td></tr>
</table>

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

b Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

								assessment of the active substance. (b) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.
		Relevant impurity	Acetic acid	5,74–51			3	The authorisations of biocidal products are subject to the following conditions: (a) The product assessment shall pay particular attention to the exposures, the risks
		Relevant impurity	Octanoic acid	1,63–9,03				

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

b Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

						(b)	and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.
					4		The authorisations

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

b Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).